DURIE TANGRI LLP
DARALYN J. DURIE (SBN 169825)
ddurie@durietangri.com
217 Leidesdorff Street
San Francisco, CA 94111
Telephone: (415) 362-6666
Facsimile: (415) 236-6300

HILLIARD & SHADOWEN LLP
STEVE D. SHADOWEN (*pro hac vice*)
steve@hilliardshadowenlaw.com
1135 W. 6th Street, Suite 125
Austin, TX 78703
Telephone: (855) 344-3298
Facsimile: (361) 882-3015

HAGENS BERMAN SOBOL SHAPIRO LLP
STEVE W. BERMAN (*pro hac vice*)
steve@hbsslaw.com
1301 Second Avenue, Suite 2000
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Interim Co-Lead Class Counsel

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PETER STALEY, et al.,

Plaintiffs,

v.

GILEAD SCIENCES, INC., et al.,

Defendants.

Case No. 3:19-cv-02573-EMC

FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. JURISDICTION AND VENUE 6

III. INTRADISTRICT ASSIGNMENT 6

IV. THE PARTIES 6

V. SCIENCE BACKGROUND 15

VI. REGULATORY BACKGROUND 21

A. Approval of Generic Drugs and Substitution of Generics for Branded Drugs 21
B. The Hatch-Waxman Amendments 22
C. Paragraph IV Certifications 23
D. Approvals Under 21 U.S.C. § 355(b)(2) 24
E. New Chemical Entity Exclusivity 25
F. Effects of AB-Rated Generic Competition 26

VII. DEFENDANTS' ANTICOMPETITIVE CONDUCT 27

A. Unlawful No-Generics Restraints: Gilead and BMS 28
B. Unlawful No-Generics Restraints: Gilead and Janssen 34
C. The No-Generics Restraints Contain Virtually Identical Terms 40
D. Increased Prices and Reduced Innovation 41

1. The No-Generics Restraints increased prices. 41
2. The No-Generics Restraints reduced innovation. 46

a. Reduced innovation by Gilead's competitors 46
b. Reduced innovation by Gilead 47

i. Delaying TAF in 2003-2004 48
ii. Degrading Products 53

E. Gilead's Unlawful Degrading of Stribild 54
F. Gilead's Unlawful Degrading of Standalone TAF 55

1. Gilead anticompetitively withheld standalone TAF in 2015-2016. 56
2. Gilead anticompetitively withheld standalone TAF 10mg. 57
3. Gilead anticompetitively withheld an HIV indication for standalone TAF. 59
4. Gilead degraded standalone TAF with anticompetitive purpose and effect. 60

G. Gilead's Unlawful Regulatory Gaming 63

1. TAF is vulnerable to generic competition in May 2023. 64
2. Gilead withheld an HIV indication in order to impair competition. 67

H. Gilead's Anticompetitive Conduct to Delay Entry of Generic Viread, Truvada, and Atripla 68

1. Most-Favored-Entry and Most-Favored-Entry-Plus clauses delay generic entry...69
2. Gilead used MFEs and MFEPs to delay generic entry. 71

a. Teva filed the first ANDAs with Paragraph IV certifications. 71
b. Second-filers posed a threat to Teva. 73
c. Gilead gave Teva an MFEP and put MFEs in all Viread agreements. 74
d. Gilead put MFEPs and MFEs in the Truvada and Atripla agreements....76

I. Gilead's Unlawful Delay-and-Extend....78

1. In granting patent extensions, the PTO has no authority to consider anticompetitive delay tactics like Gilead's. 79
2. PTE on the TAF patents was a key part of a scheme that made sense for Gilead only because it impairs competition. 80

VIII. MARKET POWER....84

IX. MARKET EFFECTS 104

X. ANTITRUST IMPACT AND EFFECT ON INTERSTATE AND INTRASTATE COMMERCE....106

XI. CLASS ACTION ALLEGATIONS 107

XII. ONGOING AND FUTURE HARM....110

XIII. CLAIMS FOR RELIEF 113

XIV. DEMAND FOR JUDGMENT....162

XV. JURY DEMAND....163

Plaintiffs, on behalf of themselves and all others similarly situated (the "Class," as defined below), on personal knowledge with respect to facts pertaining to them and upon information and belief as to other matters, bring this class action complaint against Defendants Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, Gilead Sciences Ireland UC (together, "Gilead"), Bristol-Myers Squibb Company, E. R. Squibb & Sons, L.L.C. (together, "BMS"), Janssen R&D Ireland, Janssen Products LP, and Johnson & Johnson (together, "Janssen") (collectively, "Defendants") for damages, injunctive relief, and other relief pursuant to the federal antitrust laws and state antitrust and consumer protection laws.

I. INTRODUCTION

1. Gilead and its coconspirators have engaged in a long-running scheme to restrain competition with respect to some of the most important drugs used to treat Human Immunodeficiency Virus ("HIV") infection—a disease which, if left untreated, destroys the immune system, leading to Acquired Immunodeficiency Syndrome ("AIDS") and eventual death. Through an array of anticompetitive practices—including horizontal agreements constituting per se violations of the antitrust laws—Gilead has acquired and maintained a monopoly in the market for drugs that comprise the modern HIV treatment regimen known as "combination antiretroviral therapy" ("cART"). The scheme has enabled Gilead and its coconspirators to unlawfully extend patent protection for their drugs, impair entry by would-be generic competitors, and charge exorbitant, supracompetitive prices for the drugs that people living with HIV need to survive.

2. Gilead dominates the class of drugs that target HIV known as "antiretrovirals," which are essential to effective HIV therapy. Modern antiretroviral drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." These antiretroviral cocktails are known as cART regimens. During most of the relevant time, Gilead was the exclusive maker (and is still the dominant maker) of one of the principal NRTIs used in cART regimens: Tenofovir. By controlling the market for Tenofovir, and through its collusive agreements with its coconspirators, Gilead now dominates the

market for cART. Today more than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead's sales of these products in the United States alone are more than $13 billion annually.

3. Gilead maintains a stranglehold on the cART market even though Tenofovir was discovered more than 30 years ago by researchers in the Czech Republic. In 2001, Gilead began marketing its patented formulation of the compound known as tenofovir disoproxil ("TDF"), quickly reaching sales in the hundreds of millions of dollars. Gilead expected that generic manufacturers would challenge the validity of its Tenofovir patents and potentially enter the market as early as 2009. So, in order to head off the threat of generic competition, Gilead and each of its coconspirators, BMS and Janssen, entered into a series of collusive and illegal horizontal agreements providing that each coconspirator would not compete against Gilead's Tenofovir, and would effectively block other companies from competing against Tenofovir, *even after Gilead's Tenofovir patents expired.*

4. Gilead and its coconspirators coformulated TDF with the coconspirators' third agents into single pills known as fixed-dose-combination drugs ("FDCs"). Each of the joint development agreements prevented the coconspirator from creating or marketing a competing version of the FDC formulated with generic versions of Gilead's TDF even after Gilead's patents expired (hereinafter a "No-Generics Restraint"). This gave Gilead an enormous financial incentive to move prescriptions from its standalone version of TDF to the FDCs, which would be insulated from generic competition even after TDF's patents expired. And it meant that Gilead's most likely competitors—the companies that could formulate FDCs with generic alternatives to TDF—had instead promised not to compete with Gilead. In exchange, the No-Generics Restraints and joint development agreements enabled Gilead and the coconspirator to share the artificially inflated profits from each other's sales.

5. As part of the unlawful scheme's quid pro quo, Gilead also agreed to shield BMS and Janssen's HIV drugs from imminent generic competition by allowing them to coformulate FDCs that combined their vulnerable products with a Gilead booster drug, Cobicistat, which enjoyed much longer patent protection. Just as BMS and Janssen agreed not to market a competing FDC even after Gilead's patents expired, Gilead returned the favor by agreeing not to market a competing FDC after the BMS and Janssen patents expired.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.